



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,833	06/10/2002	Howard Green	H0535/7013	5763
23628	7590	07/05/2005	EXAMINER	
WOLF GREENFIELD & SACKS, PC FEDERAL RESERVE PLAZA 600 ATLANTIC AVENUE BOSTON, MA 02210-2211			NAFF, DAVID M	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 07/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/031,833	GREEN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	David M. Naff	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### **Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 28 April 2005.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 1-13,20,22 and 74-77 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-13,20,22 and 74-77 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_\_.  
\_\_\_\_\_

**DETAILED ACTION**

A response of 4/28/05 to a restriction requirement of 3/24/05 elected Group I claims 1-13, 20 and 22 with traverse.

A preliminary amendment of 4/2/05, canceled claims 17, 23, 34, 45 and 59 (claims 14-16, 18, 21, 24-33, 35-44, 46-58 and 60-73 previously canceled), and added new claims 74-77 depending on claims 9 and 20. Since new claims 74-77 are dependent on claims in Group I, claims 74-77 are included in Group I.

The traversal of the restriction requirement is moot since all 10 non-elected claims in Groups II and III have been canceled.

Claims examined on the merits are 1-13, 20, 22 and 74-77, which are all claims in the application.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 15 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

20 Claims 1-13, 20, 22 and 74-77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

25 In line 4 of claim 1 and where required in claims 9 and 20, "Group A" is uncertain as to meaning and scope. It is uncertain as to moieties that are Group A and not Group A. If Group A is the moieties

Art Unit: 1651

on page 3 of the specification, the claims should require a Markush group of moieties recited on page 3.

In claim 2 and where required in claims 11 and 77, it is uncertain as to an agent that is a "bulking agent", "depilatory agent" 5 and "film forming agent". Agents that do and do not function as bulking, depilatory and film forming is uncertain. Additionally, bridging the last two lines of claim 2, "component of high affinity noncovalent coupling" is unclear as to components required and not required. Having high affinity is relative and subjective.

10 In claims 4 and 13, the abbreviations "OPAA" and "OPA" should be replaced with the full name to be clear as to the type of enzyme claimed.

Dependent claims 8 and 76 are confusing by not having clear antecedent basis in the claims on which they depend for 15 dihydroxyacetone being a reactive moiety.

In the last line of claim 9, there is not clear antecedent basis for "said crosslinking".

In line 2 of claim 10, "integument" is uncertain as to meaning and scope. Material that is and is not an integument is uncertain. 20 Additionally, the purpose for reciting "and" between hair and nails is uncertain since other members are present in the Markush group. In a Maukush group, "and" should be recited only before the last member.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the 25 basis for all obviousness rejections set forth in this Office action:

Art Unit: 1651

5 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering 10 patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of 15 each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claim Rejections - 35 USC § 102**

20 The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

25 (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application 30 designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 5-7, 9-11, 20, 74, 75 and 77 are rejected under 35 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Green et al (6,267,957 B1).

Art Unit: 1651

The claims are drawn to a composition, method of attaching an agent to a body tissue and pharmaceutical composition requiring a compound containing an agent having a reactive group attached by a linker or bond.

5        Green et al disclose attaching agents to proteinaceous material such as body tissue. The agent can be provided with a functional group to facilitate attachment (col 9, lines 21-25). Functional groups can be provided by reacting the agent with a bifunctional cross-linker (col 9, lines 34-40). The cross-linker can be  
10      disuccinimidyl suberate or bis(sulfosuccinimidyl) suberate (col 9, lines 45-47).

When providing the agent of Green et al with a function group using disuccinimidyl suberate or bis(sulfosuccinimidyl) suberate, a compound, compositions and method as required by the present claims  
15      will result. The agent of Green et al can be an enzyme (col 6, line 57) or a nonprotein (col 27, line 28), can be in a pharmaceutical composition (col 13, line 29), and a microparticle does not have to be present. Green et al intend using agent in a method of attaching the agent to tissue. Furthermore, it would have been obvious to select  
20      disuccinimidyl suberate or bis(sulfosuccinimidyl) from the cross-linkers disclosed by Green et al to provide a functional group on the agent, and use the functional group-containing agent for attaching to tissue or in a pharmaceutical composition as suggested by Green et al.

***Claim Rejections - 35 USC § 103***

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Green et al.

The claim requires the composition containing the compound to be 5 in a kit having instructions.

Green et al disclose providing a kit (col 2, line 31).

When providing the agent of Green et al with a functional group using disuccinimidyl suberate or bis(sulfosuccinimidyl), it would have been obvious to put the functionalized agent in a kit for later use.

10 Putting instructions on the kit would have been obvious to enable one to use the kit properly.

***Claim Rejections - 35 USC § 103***

Claims 3, 4, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green et al in view of Cheng et al 15 (6,080,566).

The claims require the agent to be an enzyme that degrades nerve agents. The enzyme can be OPAA anhydrolase or OPA anhydrase.

Green et al is described above.

Cheng et al disclose degrading nerve agents with OPAA or OPA (col 20 1, lines 50-55).

It would have been obvious to use as the enzyme agent of Green et al an OPAA or OPA enzyme to obtain its function to degrade a nerve agent as suggested by Cheng et al.

**Claim Rejections - 35 USC § 103**

Claims 8 and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green et al in view of Fusaro (3,920,808).

The claims require dihydroxyacetone as a functional moiety of the 5 compound.

Green et al is described above.

Fusaro discloses dihydroxyacetone as being reactive with amino derivatice of protein in human skin (col 2, lines 52-65).

It would have been obvious to use dihydroxyacetone to provide a 10 function group on the agent of Green et al to obtain the function of the dihydroxyacetone to react with protein as disclosed by Fusaro.

**Conclusion**

Any inquiry concerning this communication or earlier 15 communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this 20 application or proceeding is assigned is 751-273-8300.

Art Unit: 1651

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for 5 unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

10



David M. Naff  
Primary Examiner  
Art Unit 1651

DMN  
6/30/05